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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/281,474	03/30/1999	MILIND RAJOPADHYE	DM-6958	7274

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/22/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/281,474

Applicant(s)

RAJOPADHYE ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-35 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-35, and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the acceptable RCE filed 6/30/03, Paper No. 30. In addition, the Examiner acknowledges receipt of Paper No. 28, filed 5/21/03, wherein claims 1, 2, and 4-16 were amended.

Note: Claims 1-10, 12-35, and 48-50 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 5/21/03 (Paper No. 28) to the rejection of claims 1-35 and 48-50 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed non-persuasive for the reasons set forth below.

Double Patenting Rejection

The provisional rejection of claims 1-10, 12-35, and 48-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending application numbers 09/465,300; 09/466,582; 09/599,364; 09/281,209; and 09/948,807 are MAINTAINED for reason of record in the office action mailed 7/2/02, Paper No. 22.

Note: It is duly noted that Applicant intends to rebut the double patenting rejections once all other rejections are withdrawn.

103 Rejection

The rejection of claims 1, 2, 12-15, 17, 19-23, 25, 27, 28, 31-35, 48, and 49 under 35 USC 103(a) is MAINTAINED as being unpatentable over Palladino et al (US

Patent No. 5,780,426) for reasons of record in the office actions mailed 7/2/02 and 1/13/03, Paper Nos. 22 and 27, respectively.

Applicant asserts that the claims have been amended to overcome the cited reference since Palladino et al fail to teach that chelators may be attached to peptides.

It is duly noted that Applicant has amended the independent claim to state that a linking group having a specific formula (see independent claim 1). However, Applicant has allowed for all of the variables to be zero; thus, the compound can comprise a peptide targeting moiety and a chelator. While Applicant asserts that Palladino et al fail to disclose a method or procedure for the attachment of chelators to the peptide, Applicant is reminded that a reference is not limited to working examples/preferred embodiments, but must be evaluated for what it teaches those of ordinary skill in the art. In other words, a reference is evaluated for what it teaches as a whole. Hence, while Palladino et al does not focus on the attachment of the chelator to the peptide, in column 16, lines 62-66, it discloses that in general, if it is desired to increase the absorption of the peptide, a penetration enhancer may be utilized. The list of possible enhancers includes chelators. Thus, a skilled practitioner would be motivated to incorporate a chelator into the compound of Palladino et al for increased absorption of the peptide through ocular, buccal, transdermal, rectal, nasal inhalation, or oral inhalation as set forth in the document (column 16, lines 62-66).

NEW GROUNDS OF REJECTION

112 Second Paragraph Rejections

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10, 12-35, and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are confusing because the claims have been amended to state that the compound has a linking group of the formula as set forth in independent claim 1. The original present claims were directed to a compound comprising 0 – 1 linking groups. Furthermore, it is noted that prior art was cited against Applicant claims when the linking group was absent. However, when the variables g , h , g' , k , h' , g'' , h'' , and g''' are all zero, there is no linking group present. If Applicant intended for a linking group to be present, then all of the variables cannot independently be 0-2, 0-5, and 0-10. In other words, the claim contains no proviso that all the variables cannot be zero.

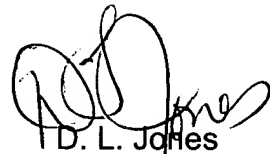
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

September 15, 2003